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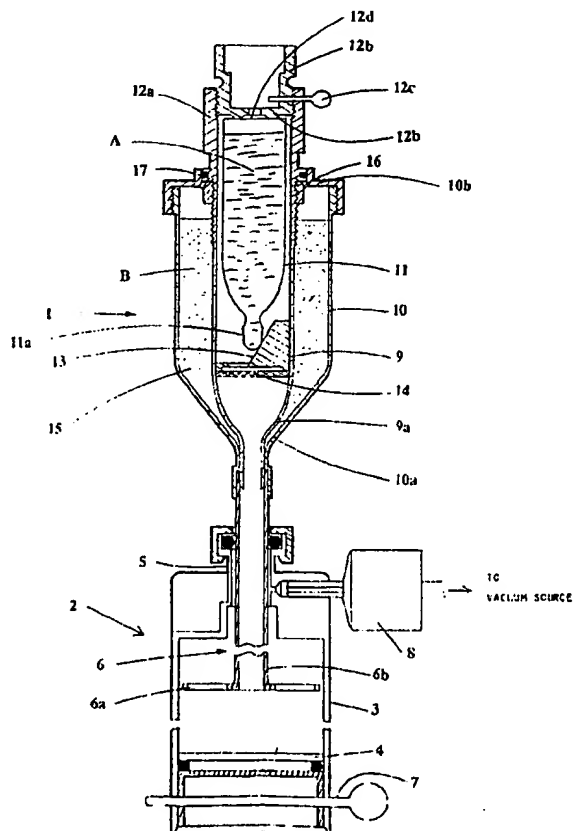
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(54) Title: METHOD AND DEVICE FOR FEEDING COMPONENTS FOR BONE CEMENT INTO A MIXING VESSEL FOR THESE

(57) Abstract

The invention relates to a method and an arrangement for successively feeding batches into a mixing vessel (2) under partial vacuum for the preparation of bone cement. The arrangement (1) comprises, on the one hand, an inner container (9) communicating with the atmosphere and with the mixing vessel (2), which container is so arranged as to enclose a glass ampoule (11) containing a liquid bone cement component (A) and, on the other hand, a device (13a) for opening the ampoule (11) so that its contents, under the effect of the partial vacuum inside the mixing vessel (2), can be sucked down into it. An outer container (10) encloses the inner container (9) at least partially and is so arranged as to communicate with the mixing vessel (2). Together with the inner container (9), the outer container (10) defines a space (15) filled with a certain quantity of a second bone cement component (B) in powder form. The inner container (9) is capable of displacement relative to the outer container (10) between a first position, in which sections of the inner container prevent communication between the mixing vessel (2) on the one hand and the atmosphere on the other hand, and a second position, in which communication between both the mixing vessel (2) and the atmosphere is open, so that the bone cement component (B) in powder form, under the effect of the partial vacuum inside the mixing vessel (2), can be sucked down into it. Feeding of the bone cement components (A, B) can take place in an arbitrary sequence.



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Method and device for feeding components for bone cement into a mixing vessel for these

The present invention relates to a method for successively feeding batches of constituent components into a mixing vessel for the preparation of bone cement under vacuum. The invention also relates to an arrangement for successively
5 feeding batches of constituent components into a mixing vessel under partial vacuum for the preparation of bone cement.

Bone cement is prepared by mixing polymethyl methacrylate in
10 powder form and liquid monomethyl methacrylate in a mixing container. Both the liquid component and the mixture give off substances in gaseous form which are environmentally harmful and injurious to the health. It is important for this reason for both the introduction of the bone cement components into
15 the mixing container and the mixing process itself to take place in such a way that the smallest possible quantity of the gases that are injurious to the health escapes into the surrounding environment. Mixing vessels by means of which both the introduction of the components and the preparation
20 of bone cement can be performed without the release of the aforementioned gases to a significant degree are described in SE-C-8901599-4 and SE-A0-9201353-1, for example.

In order for the bone cement to develop optimal strength
25 during use, it is also important for the components contained in the cement to have predetermined proportions.

The object of the present invention is to make available a method of the kind described by way of introduction, which
30 avoids the risk of gas release when feeding the bone cement components into the mixing vessel. This is achieved in accordance with the invention in that, according to the method and in an arbitrary sequence, a glass ampoule containing a liquid bone cement component surrounded by an
35 inner container communicating with the atmosphere and with

the mixing vessel is opened so that the contents of the ampoule, under the effect of the partial vacuum inside the mixing vessel, can be sucked down into it, in that a space formed by the spaces between the aforementioned inner container and by the outer container that encloses it at least partially and filled with a bone cement component in powder form is caused by displacement of the inner container relative to the outer container to move from a first position in which the space does not communicate with the atmosphere or the mixing vessel to a second position in which it communicates with the atmosphere and the mixing vessel, so that the bone cement component in powder form can be sucked down into the mixing vessel under the effect of the partial vacuum inside it.

15 An arrangement in accordance with the invention is characterized in that it comprises, on the one hand, an inner container communicating with the atmosphere, which is so arranged as to enclose a glass ampoule containing a liquid bone cement component, and as to communicate with the aforementioned mixing vessel, and comprising means for opening the ampoule so that its contents, under the effect of the partial vacuum inside the mixing vessel, can be sucked down into it and, on the other hand, an outer container enclosing the inner container at least partially and so arranged as to communicate with the mixing vessel and the atmosphere, which outer container, together with the inner container, defines a space filled with a certain quantity of a bone cement component in powder form, and in which the inner container is capable of displacement between a first position, in which sections of the inner container prevent communication between both the mixing vessel and the atmosphere, and a second position, in which communication between the mixing vessel on the one hand and the atmosphere on the other hand is open, so that the bone cement component in powder form, under the effect of the partial vacuum inside the mixing vessel, can be sucked down into it.

Especially advantageous forms of the arrangement in accordance with the invention can be appreciated from the relevant Patent Claims.

5 The invention is described below in greater detail with reference to the accompanying drawing, in which Fig. 1 illustrates schematically in longitudinal section an embodiment of a feed arrangement in accordance with the invention filled with bone cement components in liquid and
10 powder form respectively and attached to a mixing vessel. Fig. 2 illustrates the feeding of the liquid bone cement component into the mixing vessel, and Fig. 3 illustrates the feeding of the bone cement component in powder form into the mixing vessel. Figures 4-6 illustrate, in a corresponding
15 fashion to Figures 1-3, an alternative embodiment of a feed arrangement in accordance with the invention.

The designations 1 and 2 are used generally in the drawing in respect of a feed arrangement and a mixing vessel. The former
20 comprises a cylindrical container 3 with a bottom 4 at one end and a neck 5 with an opening at the other end, together with an agitator 6 capable of axial movement in the container 3 consisting of an agitator disc 6a and a tubular agitator rod 6b. This is mounted so that it is free to slide and to
25 produce a seal in the neck 5, in such a way that the agitator 6 can be used to bring about mixing of the bone cement components. Once mixing is complete, and once a lock 7 has been removed, the bottom 4 can be displaced axially in the manner of a piston towards the neck 5 for the purpose of
30 discharging the bone cement via the agitator rod 6b, which now serves as a discharge nozzle. The interior of the container 3 communicates via a filter 8 with a vacuum source (not shown) during feeding of the bone cement components and during mixing of these. Rapid and effective feeding of the
35 bone cement components into the mixing vessel, and safe handling of the gases that are environmentally harmful and injurious to the health, are achieved in this way.

The feeding of the bone cement components from the feed arrangement 1 into the mixing vessel takes place via the agitator rod 6b in a way that will be described later.

- 5 The feed arrangement 1 comprises an inner, essentially cylindrical container 9 communicating with the atmosphere and an outer, similarly essentially cylindrical container 10 enclosing the inner container at least partially. The container 9 is so arranged as to enclose a glass ampoule 11 containing the liquid bone cement component, and as to communicate with the mixing vessel 2, as already mentioned, via its agitator rod 6b. For the purpose of breaking the ampoule 11, the container 9 has a cylindrical part 12a at the end situated at the top in the drawing with a bottom 12b capable of axial displacement relative to it.

In the embodiment illustrated in the drawing, the facility for displacement to take place between the cylindrical part 12a and the bottom 12b is achieved by means of threads engaging in one another, in conjunction with which the bottom 12b has an opening 12d between the interior of the container 9 and the atmosphere, and the container 9 has a funnel-shaped part 9a at the end situated at the bottom in the drawing, the narrowest part of which discharges above the agitator rod 6b. In the embodiment in accordance with Figures 1-3, the tip of the glass ampoule 11 points downwards, and there is present inside the inner container 9 an oblique plane 13, against which the tip 11a of the glass ampoule 11, which has a fractural impression, rests. As the bottom 12b of the inner container 9 is screwed downwards, the tip 11a is eventually broken off against the oblique plane 13, and the contents of the ampoule are sucked down into the mixing vessel 2 by the partial vacuum inside it, as illustrated in fig. 2. A filter 14 is provided for the purpose of preventing glass splinters from the glass ampoule 11 from accompanying its contents down into the mixing vessel 2. In the embodiment in accordance with Figures 4-6, the tip 11a of the glass ampoule points upwards, and the inner container 9 has an

upward-facing pointed cone 13a, against which the bottom 11b of the glass ampoule rests. As the bottom 12b of the inner container 9 is screwed downwards, the bottom 11b of the glass ampoule 11 is penetrated by the cone 13a and, as previously
5 described for the embodiment in accordance with Figures 1-3, the contents of the glass ampoule are sucked down into the mixing vessel 2. As the liquid bone cement component in the glass ampoule 11 is flowing down into the mixing vessel 2, air is sucked in via the opening 12d, thereby preventing the
10 gases from the liquid bone cement component from finding their way into the atmosphere.

The outer container 10 is essentially identical in shape to the inner container 9, is so arranged as to be capable of
15 being in contact with the mixing vessel 2 in a similar fashion to the inner container 9, has a lower funnel-shaped part 10a, and has a diameter larger than the inner container 9, so that a space 15 for the bone cement component in powder form is formed between the containers 9, 10. The bottom 10b
20 of the outer container 10 is in threaded engagement with the inner container 9, so that the latter can be displaced axially from a position shown in Figures 1 and 2, in which the funnel-shaped parts 9a, 10a of the containers 9, 10 form a closure of the space 15 to a position shown in Fig. 3, in
25 which the space 15 communicates with the inside of the mixing vessel. In the latter position, a duct 16 is opened so that the space 15 also communicates with the atmosphere, for the purpose of facilitating the introduction of the bone cement component in powder form achieved through the partial vacuum
30 inside the mixing vessel, and of preventing the aforementioned gases from finding their way into the atmosphere. An annular seal 17 provides sealing in the first-mentioned position between the upper container 9 and the bottom 10b of the outer container 10.

35

The embodiment in accordance with Figure 6 differs from the embodiment in Figures 4, 5 through brush-shaped devices 9b so arranged as to make contact with the surface of the funnel-

shaped part 10a. The bone cement component B is released from the aforementioned surface by relative rotation between the outer and inner container.

- 5 A feed procedure is now summarized below with reference to the Figures in the drawing.

The feed arrangement in accordance with the invention is supplied ready for use, i.e. filled with the bone cement
10 components in the correct proportions.

In order to permit feeding of the bone cement components into the mixing vessel 2 from the feed arrangement 1 in accordance with the invention, the mixing vessel 2 is required to be
15 connected to an active vacuum source. The pin 12c is first removed, and the displaceable bottom 12b is screwed downwards, in conjunction with which the glass ampoule is caused to move downwards. Screwing continues until the tip 11a of the glass ampoule 11 is broken off against the oblique
20 plane 13, see Fig. 2, or until the bottom 11b of the glass ampoule is penetrated by the tip of the cone 13a; see Fig. 5. The liquid bone cement component now flows down into the mixing chamber 2 under the effect of the partial vacuum inside it. Once the glass ampoule 11 is totally empty, the
25 cylindrical part 12a is rotated so that the inner container 9 is displaced upwards from the position shown in Figures 1 and 2, in which the space 15 containing the bone cement component in powder form is closed both at the top and at the bottom, to the position shown in Figure 3, in which the
30 aforementioned space is open both at the top, via the duct 16, and at the bottom. Once the space 15 has been completely emptied, the feed arrangement 1 is removed, and the inner tubular part of the agitator rod is sealed with a sealing rod which seals against the mouth of 6a. The mixing procedure can
35 now start.

The feed arrangement in accordance with the invention can be modified in many ways within the scope of the idea of

invention. This is true, for example, of the facility for axial displacement between the inner container 9 and its bottom 12b, and between the inner container 9 and the outer container 10, which facility for axial displacement can be
5 achieved other than by threaded engagement. Means other than the oblique plane 13 and the pointed cone 13a can be considered for the purpose of opening the ampoule 11.

The emptying sequence can also take place in the reverse
10 order to that described above, i.e. first the bone cement component in powder form, and then the liquid bone cement component.

Patent Claims

1. Method for successively feeding batches of constituent components (A, B) into a mixing vessel (2) for the preparation of bone cement under vacuum, *characterized* in that, in an arbitrary sequence, a glass ampoule (11) containing a liquid bone cement component (A) surrounded by an inner container (9) communicating with the atmosphere and with the mixing vessel is opened so that the contents of the ampoule, under the effect of the partial vacuum inside the mixing vessel (2), can be sucked down into it, in that a space (15) formed by the spaces between the aforementioned inner container and by the outer container (10) that encloses it at least partially and filled with a bone cement component (B) in powder form is caused by displacement of the inner container (9) relative to the outer container (10) to move from a first position in which the space does not communicate with the atmosphere or the mixing vessel (2) to a second position in which it communicates with the atmosphere and the mixing vessel, so that the bone cement component (B) in powder form can be sucked down into the mixing vessel (2) under the effect of the partial vacuum inside it.
2. Arrangement for successively feeding batches of constituent components (A, B) into a mixing vessel (2) for the preparation of bone cement under vacuum, *characterized* in that the arrangement (1) comprises, on the one hand, an inner container (9) communicating with the atmosphere, which is so arranged as to enclose a glass ampoule (11) containing a liquid bone cement component (A) and as to communicate with the aforementioned mixing vessel (2), and comprising means (13; 13a) for opening the ampoule (11) so that its contents, under the effect of the partial vacuum inside the mixing vessel (2), can be sucked down into it and, on the other hand, an outer container (10) enclosing

the inner container (9) at least partially and so arranged as to communicate with the mixing vessel (2) and the atmosphere, which outer container, together with the inner container (9), defines a space (15) filled with a certain quantity of a bone cement component (B) in powder form, and in which the inner container (9) is capable of displacement between a first position, in which sections of the inner container prevent communication between both the mixing vessel (2) and the atmosphere, and a second position, in which communication between the mixing vessel (2) on the one hand and the atmosphere on the other hand is open, so that the bone cement component (B) in powder form, under the effect of the partial vacuum inside the mixing vessel (2), can be sucked down into it, in conjunction with which feeding of the components (A, B) into the mixing vessel can take place in an arbitrary sequence.

3. Arrangement in accordance with Patent Claim 1, *characterized* in that the inner container (9) has a cylindrical part at the top, with a bottom (12b) capable of axial displacement relative to it, which bottom exhibits an opening (12d) between the interior of the container (9) and the atmosphere, and has a funnel-shaped part (9a) at the bottom adjacent to the cylindrical part, the downward-facing narrowest part of which is designed to communicate with an opening in the mixing vessel (2), in conjunction with which the glass ampoule (11), which has a downward-facing tip (11a) executed with a fractural impression, rests with the latter against an oblique plane (13) arranged inside the inner container (9), and is clamped between the former and the bottom (12b), so that as the latter is displaced successively downwards, the tip (11a) of the ampoule is broken off, and the liquid bone cement component (A) can be sucked down into the mixing vessel (2) by the partial vacuum inside it, and in that the

outer container (10) has a cylindrical part and an upward-facing bottom (10b), in which the inner container (9) with its cylindrical part is mounted in such a way as to be capable of displacement between the
5 aforementioned positions, and a funnel-shaped part (10a) adjacent to the cylindrical part, the downward-facing, narrowest part of which is intended to be connected to the aforementioned opening in the mixing vessel (2), in conjunction with which the funnel-shaped part (9a) of the inner container (9) is so
10 arranged, in the first position, through contact with the funnel-shaped part (10a) of the outer container (10), as to prevent communication between the inner space (15) of the outer container (10) and the mixing
15 vessel (2).

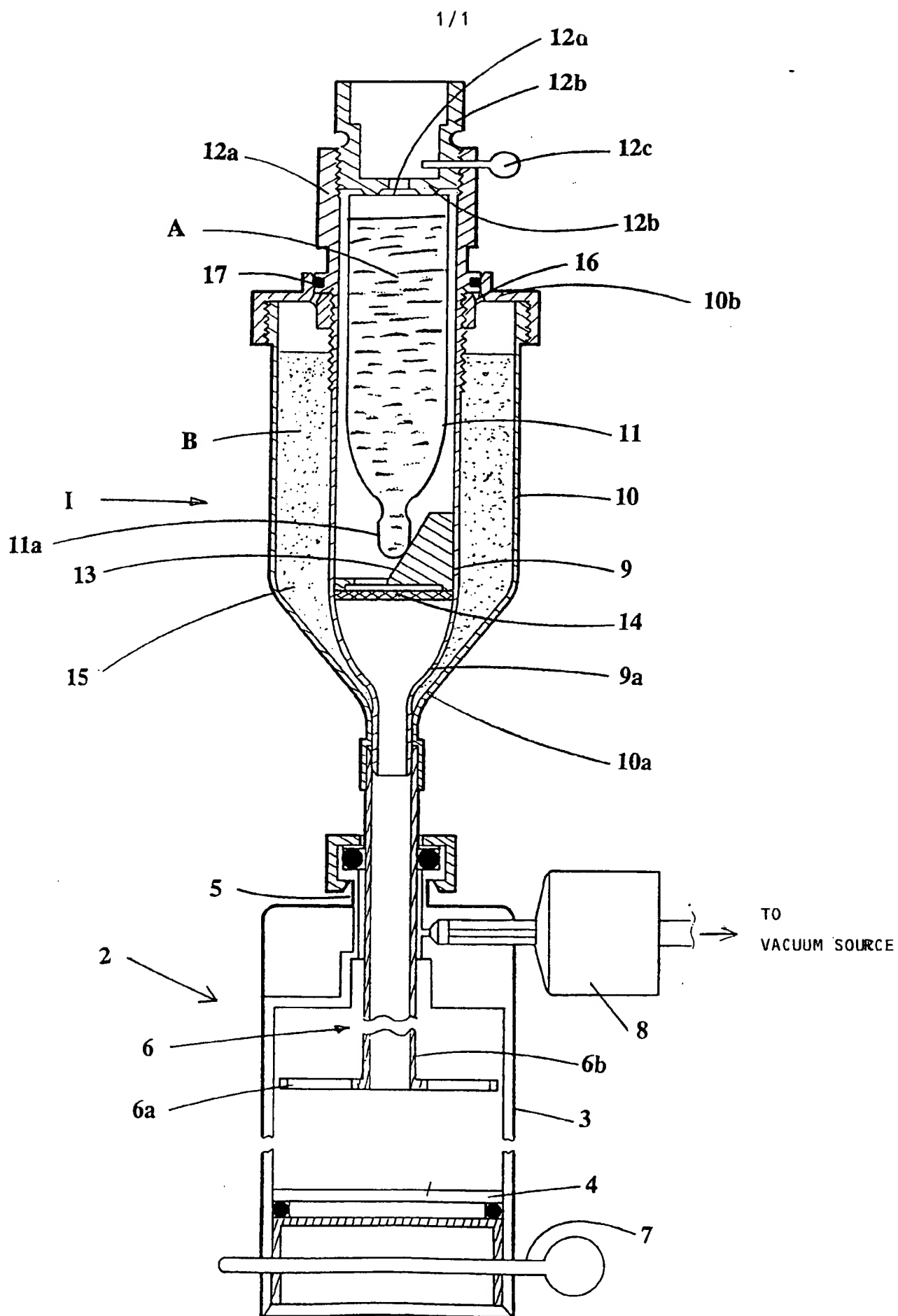
4. Arrangement in accordance with Patent Claim 2, **characterized** in that the inner container (9) has a cylindrical part at the top, with a bottom (12b) capable of axial displacement relative to it, which
20 bottom exhibits an opening (12d) between the interior of the container (9) and the atmosphere, and has a funnel-shaped part (9a) at the bottom adjacent to the cylindrical part, the downward-facing narrowest part
25 of which is designed to communicate with an opening in the mixing vessel (2), in conjunction with which the bottom (11a) of the glass ampoule rests against a cone (13a) arranged inside the inner container (9), and is clamped between the former and the bottom (12b), so
30 that, as the latter is successively displaced downwards, the bottom (11b) of the ampoule is penetrated and broken, and the liquid bone cement component (A) can be sucked down into the mixing vessel (2) by the partial vacuum inside it, and in that the
35 outer container (10) has a cylindrical part and an upward-facing bottom (10b), in which the inner container (9) with its cylindrical part is mounted in such a way as to be capable of displacement between the

5 aforementioned positions, and a funnel-shaped part
 (10a) adjacent to the cylindrical part, the downward-
 facing, narrowest part of which is intended to be
 connected to the aforementioned opening in the mixing
10 vessel (2), in conjunction with which the funnel-
 shaped part (9a) of the inner container (9) is so
 arranged, in the first position, through contact with
 the funnel-shaped part (10a) of the outer container
 (10), as to prevent communication between the inner
15 space (15) of the outer container (10) and the mixing
 vessel (2).

5. Arrangement in accordance with Patent Claims 2, 3 or
 4, *characterized* in that there is present between the
15 bottom (10b) of the outer container (10) and the
 cylindrical part of the inner container (9) an opening
 (16) so arranged as to be closed in the aforementioned
 first position and as to be opened successively as the
 inner container (9) is displaced towards the second
20 position.

6. Arrangement in accordance with one or other of the
 preceding Patent Claims, *characterized* in that a filter
 (14) is arranged beneath the ampoule (11), i.e. between
25 it and the opening from the inner container (9) to the
 mixing vessel (2).

7. Arrangement in accordance with one or other of the
 preceding Patent Claims, *characterized* in that the
30 inner container is executed in the vicinity of its
 funnel-shaped part (9a) with brush-like devices (9b)
 in contact with the funnel-shaped part (10a) of the
 outer container (10) and so arranged as to release the
 bone cement component (B) in powder form from the
35 funnel-shaped part (10a).



INTERNATIONAL SEARCH REPORT

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PCT/SE 94/00415

A. CLASSIFICATION OF SUBJECT MATTER

IPC 5: B01F 15/02, A61F 2/46

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 5: B01F, A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

SE,DK,FI,NO classes as above

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DIALOG

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US, A, 4973168 (KWAN-HO CHAN), 27 November 1990 (27.11.90), figure 1, abstract -----	1,2



Further documents are listed in the continuation of Box C.



See patent family annex.

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